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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/024,339	12/21/2001	Vincenzo Cannata	217689US40	4736

22850 7590 12/21/2004

OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C.  
1940 DUKE STREET  
ALEXANDRIA, VA 22314

EXAMINER

DELACROIX MUIRHEI, CYBILLE

ART UNIT PAPER NUMBER

1614

DATE MAILED: 12/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/024,339

Applicant(s)

CANNATA ET AL.

Examiner

Cybille Delacroix-Muirheid

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 20 May 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 19-29, 31, 34-37, 56-64, 74-85 is/are pending in the application.
- 4a) Of the above claim(s) 56-64 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 19-29, 31, 34-37, 74-85 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_.

***Detailed Action***

1. Claims 19-28, 31, 34-37 (74-85) are rejected under 35 U.S.C. 103(a) as being unpatentable over Singer et al., 6,531,509 B2 in view of Satzinger et al., 4,024,175 and Jennings et al., 5,693,845.
2. Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Singer et al. in view of Satzinger et al. and Jennings et al. as applied to claims 19-28, 30-37 above, and further in view of Augart et al.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

New claims 74-85 fall under the previous claim rejections under 35 USC 103 for reasons already of record. However, comments with respect to these claims will be made below.

***Response to Amendment(s)***

The following is responsive to Applicant's amendment received May 20, 2004.

Claims 1-18, 30, 32-33, 38-55, 65-73 are cancelled. New claims 74-85 are added. Claims 19-29, 31, 34-37, 56-64, 74-85 are currently pending. Claims 56-64 are withdrawn from consideration.

The previous claim objections set forth in paragraph 1 of the office action mailed Nov. 21, 2003 **is withdrawn** in view of Applicant's amendment and the remarks contained therein.

The previous claim rejection under 35 USC 112, second paragraph, set forth in paragraphs 2-3 of the office action mailed Nov. 21, 2003 **is withdrawn** in view of Applicant's amendment and the remarks contained therein.

The previous rejection of claims 1-18 under 35 USC 103, set forth in paragraph 4 of the office action mailed Nov. 21, 2003 **is withdrawn** in view of Applicant's amendment and the remarks contained therein.

However, Applicant's arguments traversing the previous rejections of claims 19-28, 30-37 and 29 under 35 USC 103, set forth in paragraphs 5-6 of the office action mailed Nov. 21, 2003 have been considered but are not found to be persuasive.

Said rejections are maintained essentially for the reasons given previously in the office action mailed Nov. 21, 2003 with the following additional comment:

Applicant states that the present inventors have discovered that the presently claimed compositions are surprisingly stable despite the presence of a high amount of an anion of a mineral acid, such as chloride. The present inventors have discovered that gabapentin may be stabilized against the formation of the corresponding lactam in the presence of an anion of a mineral acid by the addition of a nonacidic cation which is an alkali metal and/or an alkaline earth metal.

Singer et al. on the other hand, actually only exemplifies the use of quaternary amines and other bases to stabilize gabapentin against the formation of the corresponding lactam in the presence of chloride anions. For example, all of Examples 1-4 and 7-11 involve the use of tributylamine. Applicant argues that Singer et al.

actually only disclose the use of a trialkylamine or some other type of base to stabilize gabapentin in the presence of high amounts of chloride.

Satzinger et al and Jennings et al. merely disclose that gabapentin can form pharmaceutically acceptable salts. There is no teaching in any of the cited references which would even remotely suggest that gabapentin could be stabilized against the formation of the corresponding lactam in the presence of an anion of a mineral acid, such as chloride, by the addition of a nonacidic cation, which is an alkali metal and/or an alkaline earth metal. It is the surprising discovery of the present inventors that it is not necessary to add a trialkylamine or some other type of base to stabilize gabapentin in the presence of an anion such as chloride. Instead, stability may be conferred by the addition of a nonacidic cation, such as an alkali metal and/or an alkaline earth metal.

Said arguments have been considered but are not found to be persuasive.

Applicant's claims recite "comprising" language, which is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. See, e.g. Invitrogen Corp. v. Biocrest Mfg., L.P., 327 F.3d 1364, 1368, 66 USPQ2d 1631, 1634 (Fed. Cir. 2003) ("The transition comprising' in a method claim indicates that the claim is open-ended and allows for additional steps."); Genentech, Inc. v. Chiron Corp., 112 F.3d 495, 501, 42 USPQ2d 1608, 1613 (Fed. Cir. 1997) ("Comprising" is a term of art used in claim language which means that the named elements are essential, but other elements may be added and still form a construct within the scope of the claim.); Moleculon Research Corp. v. CBS, Inc., 793 F.2d 1261, 229 USPQ 805 (Fed. Cir. 1986); In re Baxter, 656 F.2d 679, 686, 210 USPQ 795, 803 (CCPA 1981); Ex parte

Davis, 80 USPQ 448, 450 (Bd. App. 1948) ("comprising" leaves "the claim open for the inclusion of unspecified ingredients even in major amounts"). Please refer to MPEP 2111.03.

In this case, even though additional trialkylamine is not needed to stabilize the gabapentin in the presence of an anion such as chloride, the claims do not exclude the presence of the trialkylamine. Furthermore, stabilization of the gabapentin compositions would have been an obvious characteristic of the composition in the prior art because the combination of the prior art discloses gabapentin compositions containing a nonacidic cation such as alkali or alkaline earth metals (please refer to page 7 of the office action mailed Nov. 21, 2003).

With respect to newly added claims 74, the use of additional non-acidic excipients is taught by the prior art, especially Augart et al., where additional adjuvant materials such as cyclodextrin, lactose, etc. can be used in compositions because they do not affect the stability of gabapentin. Please refer to col. 5, lines 11-17.

Newly added claims 76-85, are encompassed and therefore obvious in view of the prior art, i.e. Singer et al. and Augart et al., which teach that the undesirable lactam content of gabapentin should not exceed 0.2% by weight and 0.5%, respectively.

***Claim Rejection(s)—35 USC 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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3. Claim 75 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 75 recites the limitation "said nonacidic cation is chloride" in lines 1-2.

There is insufficient antecedent basis for this limitation in the claim.

### ***Conclusion***

Claims 19-29, 31, 34-37, 74-85 are rejected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Cybille Delacroix-Muirheid** whose telephone number


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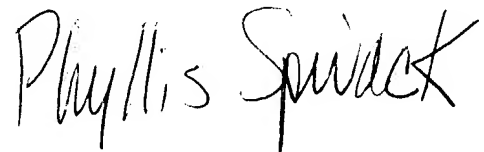
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is **571-272-0572**. The examiner can normally be reached on Mon-Thurs. from 8:30 to 6:00 as well as every other Friday from 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Christopher Low**, can be reached on **571-272-0951**. The fax phone number for the organization where this application or proceeding is assigned is **571-273-8300**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CDM   
Dec. 13, 2004



**PHYLLIS SPIVACK  
PRIMARY EXAMINER**